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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,101	02/04/2004	Jacques Seguin	P35365.03	6184

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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
04/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/772,101	SEGUIN ET AL.	
	Examiner	Art Unit	
	ANN SCHILLINGER	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *150-170* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *150-170* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 150-153, 155-163, and 165-170 are rejected under 35 U.S.C. 103(a) as obvious over Leonhardt et al. (US Pat. No. 5,957,949) in view of Gabbay (US Pat. No. 6,264,691). Leonhardt et al. teaches the following of claim 150: a prosthetic cardiac valve assembly comprising: a replacement valve (22) comprising: a plurality of leaflets through which blood is configured to selectively flow (col. 6, lines 23-34); and a plurality of commissure points (68) from which the replacement valve is suspended; a valve support (20) connected to the replacement valve (Fig. 4) and configured to be collapsible with the replacement valve for transluminal delivery, wherein outer circumferential of the valve support varies along at least some portions of the axial length (Fig. 2; col. 6 lines 19-22); wherein the valve support further comprises: a first section (lower section of element 20 as shown in its deployed state in Fig. 2) terminating in a first end, said first end comprising an outer circumference having a first diameter, said first section configured to engage the native annulus; and a second section (upper section of element 20 as shown in its deployed state in Fig. 2) terminating in a second end, said second end comprising an outer circumference having a second diameter, said second section configured to extend past the coronary ostia and into the ascending aorta; wherein the second circumference is greater than the first circumference (Fig 2).

Leonhardt et al. discloses claim 160 as follows: a prosthetic cardiac valve assembly comprising: a replacement valve (22) comprising a plurality of leaflets (col. 6, lines 23-34) and a plurality of commissure points (68) from which the replacement valve is generally suspended; and a valve support (20) having a proximal portion and a distal portion, said valve support connected to the replacement valve (Fig. 4) and configured to be collapsible for transluminal delivery; wherein the valve support is configured to extend, when implanted into a patient, from a native annulus at the proximal portion to an ascending aorta at the distal portion, past a location of the patient's coronary ostia; wherein an outer shape of the valve support varies along an axial length of said valve support such that a cross-sectional dimension of the distal portion is generally larger than a cross-sectional dimension of the proximal portion (please see Fig. 2 where the upper portion of element 20 has a greater diameter than the lower portion); wherein the valve support comprises a plurality of intersecting members forming a plurality of cells, said cells being arranged substantially uniformly around a periphery of the valve support (Fig. 1B); and wherein the plurality of cells located along the distal portion of the valve support have a larger cross-sectional size than the plurality of cells located along the proximal portion of the valve support (Fig. 2).

Leonhardt et al. discloses the following of claim 170: a prosthetic cardiac valve comprising: a replacement valve (22) comprising: a plurality of leaflets configured to permit blood to selectively flow therethrough (col. 6, lines 23-34); and a plurality of commissure points (68) from which the replacement valve is suspended; and a valve support (20) connected to the replacement valve (Fig. 4) and configured to be collapsible for transluminal delivery, wherein when the valve support is implanted in a patient and the replacement valve is positioned in a

native aortic valve annulus, said valve support is sized and shaped to extend from a position of the native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into the ascending aorta; wherein outer circumference of the valve support varies along at least some portions of the axial length (Fig. 2); wherein the valve support further comprises: a first section (lower section of element 20 as shown in its deployed state in Fig. 2) terminating in a first end, said first end comprising an outer circumference having a first diameter, said first section configured to engage the native annulus; and a second section (upper section of element 20 as shown in its deployed state in Fig. 2) terminating in a second end, said second end comprising an outer circumference having a second diameter, said second section configured to extend past the coronary ostia and into the ascending aorta; wherein the second circumference is greater than the first circumference (Fig 2).

Leonhardt et al. discloses claims 151 and 161 as shown in Figs. 2-3.

Leonhardt et al. discloses claims 152 and 162 as shown in Fig. 1B.

Leonhardt et al. discloses claims 153 and 163 in col. 5, lines 41-52.

Leonhardt et al. discloses claims 155, 156, 165 and 166 in col. 5, lines 11-22.

Leonhardt et al. discloses claims 157 and 167 in element 60 and in col. 6, lines 23-34.

Leonhardt et al. discloses claims 158 and 168 in col. 1, lines 49-58.

Leonhardt et al. discloses claims 159 and 169 in col. 10, line 53 through col. 11, line 10.

Leonhardt et al. is silent with respect to the length of the stent serving as the valve support. Gabbay teaches a stent supporting a heart valve where different stent lengths may be applied to the same heart valve structure and the stent's length would be sufficient to extend from the native annulus past the coronary ostia in columns 2-4 for the purpose of giving the stent

the length needed to properly support the tissue surrounding the heart valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the length of the stent to extend from the annulus into the ascending aorta in order to construct the stent so that it will provide additional support, as needed, to the tissue in the area where the prosthetic valve is being implanted. Also, it has been held that it would have been an obvious matter of design choice to change the size of the stent, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Claims 154 and 164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. in view of Wolff (US Pat. No. 5,104,404).

Leonhardt et al. teaches the invention substantially as claimed and described above, however, Leonhardt et al. does not teach using multiple wires to construct the valve support. Wolff teaches a stent constructed from multiple wires in col. 5, lines 10-15 for the purpose of allowing greater flexibility in the shape of the stent during its construction. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Leonhardt et al. by using multiple wires to construct the valve support stent in order to allow greater flexibility in the shape of the stent during its construction

Response to Arguments

Applicant's arguments with respect to the Andersen et al. have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 10/12/2010 have been fully considered but they are not persuasive. The Applicant contends that the Leonhardt et al. reference cannot be modified to

have a longer stent surrounding its heart valve. However, the Applicant has not provided any evidence to show how extending the length of the stent of Leonhardt et al. will destroy the device. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness. See MPEP § 716.01(c). In addition, it has been held that it would have been an obvious matter of design choice to change the size of the stent, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

/A. S./
Examiner, Art Unit 3774